

## REMARKS

### Status of the claims

Claims 1-18 are pending in the application. Claims 7-9 and 16-18 are withdrawn from consideration. Claims 1-6 and 10-15 stand rejected. No amendments are presented.

### The 35 U.S.C. §102 rejection

Claims 10-14 are rejected under 35 U.S.C. §102(b) as being anticipated by *Chiesi et al.* (WO 00/06132A2) evidenced by *Basu et al.* (US 2002/0025348A1). The Applicants respectfully traverse this rejection.

The Examiner states that *Chiesi et al.* teach a pharmaceutical formulation for the treatment of inflammatory bowel disease (IBD) containing as an active ingredient, beclomethasone dipropionate (BDP). Furthermore, *Chiesi et al.* teach that the formulation demonstrates no systemic absorption of beclomethasone dipropionate and its major active metabolites. The Examiner also states that *Basu et al.* report that irritable bowel syndrome (IBS) tends to occur in IBD patients who are in remission from their IBD symptomologies. Thus, the Examiner asserts that claim 10 is anticipated because the IBD patients disclosed by *Chiesi et al.* are the patients in need of treatment of irritable bowel syndrome because IBS tends to occur in IBD patients. Furthermore, the mechanism of action of increasing the threshold of pain to colorectal distention, thereby alleviating the symptoms of irritable bowel syndrome disease comprising identical patients having IBD who are in need of alleviating the symptoms of

irritable bowel syndrome as evidenced by *Basu et al.* The Applicants respectfully disagree.

The Applicants respectfully submit that *Chiesi et al.* disclose pharmaceutical formulations for the treatment of inflammatory bowel disease containing as active ingredient beclomethasone dipropionate. More particularly, *Chiesi et al.* disclose a formulation in the form of stable and ready-to-use enema characterized in that the homogeneity of the active ingredient at low concentration and fluidity of the suspension is optimal for promoting its retrograde progression and homogeneous distribution. *Chiesi et al.* also recite embodiments concerned with gastro-resistant modified-release tablets whose composition has been optimized in order to control the release of the active ingredient in fluids at basic pH and low ionic strength.

The Applicants respectfully submit that *Basu et al.* disclose formulations of plants and extracts thereof useful in the treatment of bowel disorders. In this regard, *Basu et al.* disclose that the formulations of their invention can be used to treat inflammatory bowel disease and related conditions such as irritable bowel syndrome and other inflammatory disorders such as arthritis (0003).

In order to anticipate a claim, a single reference must explicitly or inherently teach each and every element of the claimed invention. The Applicants respectfully submit that *Chiesi et al.* as evidenced by *Basu et al.* does not teach each and every element claimed in the instant invention, neither explicitly nor inherently. *Chiesi et al.* teach that pharmaceutical formulation for the treatment of inflammatory bowel disease (IBD) containing as an active ingredient, beclomethasone dipropionate (BDP). There is however, no teaching of irritable bowel syndrome (IBS) in *Chiesi et al.* The Examiner

argues that this deficiency is overcome by Basu *et al.* which report that IBS also tends to occur in IBD patients who are in remission from their IBD symptomologies. The Applicants submit Quigley *et al.* (Abstract), enclosed herewith, which point out that IBS and IBD have been regarded traditionally as separate disorders and despite some studies suggesting otherwise, any convergence of IBS and IBD is largely due to misdiagnosis (Quigley, Chin J Dig Dis. 2005; 6(3):122-132).

The Applicants respectfully submit a section from the NIH website, enclosed herewith, relating to digestive diseases, specifically irritable bowel syndrome (<http://digestive.niddk.nih.gov/ddiseases/pubs/ibs/#what>). The website states that "[t]hrough the years, IBS has been called by many names, among them colitis, mucous colitis, spastic colon, or spastic bowel. However, no link has been established between IBS and inflammatory bowel diseases such as Crohn's disease or ulcerative colitis."

The Applicants respectfully submit a section from the Crohn's and Colitis Foundation of America (<http://www.ccfa.org/about/news/ibsoribd>) website, enclosed herewith, which states that "[m]any people are confused about two distinct gastrointestinal disorders – IBD and IBS. Different intestinal disorders can produce similar symptoms. Irritable bowel syndrome (IBS) is a condition that produces some symptoms similar to those of inflammatory bowel disease (IBD), but they are not the same condition, and they involve very different treatments. Therefore, getting an accurate diagnosis is essential to managing your condition properly."

Furthermore, the Applicants respectfully submit that Basu *et al.* does not teach or suggest population suffering from IBD greatly overlap the population suffering from IBS as evidenced by their claim construction (claims 9 and 10, US 2002/0025348).

Claim 7 of *Basu et al.* reads, "A method for treating a bowel disorder in a mammal, said method comprising identifying the mammal as suffering from a bowel disorder; administering the composition of matter of claim 1 or 2 to the mammal." Claim 9 further limits claim 7 for cases in which the bowel disorder is IBD. Claim 10 further limits claim 7 for cases in which the bowel disorder is IBS. It is clear by *Basu et al.* claim construction that the population having IBD does not necessarily overlap the population having IBS.

In view of the arguments presented herein and the references enclosed herewith, the Applicants submit that claims 10-14 are not anticipated by *Chiesi et al.* further evidenced by *Basu et al.* Accordingly, the Applicants respectfully request the withdrawal of this rejection.

The 35 U.S.C. §103 rejection

Claims 1-6 and 15 are rejected under 35 U.S.C. §103 as being unpatentable over *Chiesi et al.* (WO 00/06132A2) in view of *Basu et al.* (US 2002/0025348A1). The Applicants respectfully traverse this rejection.

The Examiner states that *Basu et al.* teach that the pathogenesis of inflammatory bowel disease and related disorders such as irritable bowel syndrome involve inflammation. Examiner also states that *Basu et al.* teach that acute enteric inflammation in symptoms generated in irritable bowel syndrome. The Examiner further states that *Basu et al.* teach that reduction in inflammatory agents would significantly effect the treatment of inflammatory disease like irritable bowel syndrome and inflammatory bowel disease. Furthermore, the Examiner states that *Basu et al.* teach

that by treating inflammation, hyperalgesia potentate by the inflammatory factors would be prevented.

Thus, the Examiner concludes that it would have been obvious to one of ordinary skill in the art to employ beclomethasone to an individual having irritable bowel syndrome (IBS) for the treatment of such disorder because beclomethasone is effective for the treatment of inflammatory disorder related to inflammation and because irritable bowel syndrome is an inflammatory disorder as taught by **Basu et al.** The Examiner asserts that one would have been motivated to make such modification in order to achieve an expected anti-inflammatory effect of beclomethasone to halt inflammatory process generated as a symptom to irritable bowel syndrome. The Applicants respectfully disagree.

Based on the enclosed references of Quigley, NIH website, CCFA website and **Basu et al.** claim construction, discussed *supra*, the Applicants submit that IBS and IBD are distinct disorders that do not affect significantly the same population. In fact, art at the time the invention was filed and even today, teach that IBS and inflammatory bowel disease are distinct clinical syndromes in variety of aspects. Thus, there is ample evidence to show that IBS and Inflammatory disease are distinct.

Furthermore, the Applicants submit that **Chiesi et al.** only teach the use of topically active corticosteroid such as beclomethasone dipropionate in the treatment of inflammatory bowel diseases such as Ulcerative colitis and Crohn's disease. In this regard, **Chiesi et al.** disclose rectal or oral administration of beclomethasone dipropionate. There is no teaching or suggestion in **Chiesi et al.** that the administration of beclomethasone dipropionate is effective in treating irritable bowel syndrome. **Basu et al.**

do not cure this deficiency for the following reasons. First, the information in the art at the time of filing of the instant invention which teaches that IBS and IBD are distinct diseases and the population of people suffering IBS and IBD do not overlap as evidenced by Basu *et al.* claim construction. Second, there is a lack of histological evidence of inflammation in IBS. Evidence has been provided that those skilled in the art generally believe these two disorders to be unlinked and that IBS is not inflammatory disorder as the Examiner asserts.

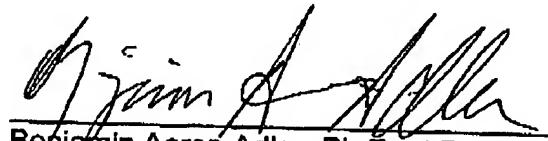
In view of the arguments presented herein and the references enclosed herewith, the Applicants respectfully request the withdrawal of rejection of claims 1-6 and 15 under 35 U.S.C. 103.

This is intended to be a complete response to the Final Office Action mailed January 23, 2009. If any issues remain outstanding, please telephone the undersigned attorney of record for immediate resolution.

Respectfully submitted,

Date:

4/21/09



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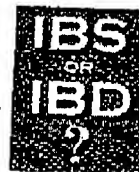
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## IBS and IBD: Two Very Different Disorders

Many people are confused about two distinct gastrointestinal disorders -- IBD and IBS. Different intestinal disorders can produce similar symptoms. *Irritable bowel syndrome* (IBS) is a condition that produces some symptoms similar to those of *inflammatory bowel disease* (IBD), but they are not the same condition, and they involve very different treatments. Therefore, getting an accurate diagnosis is essential to managing your condition properly. The following Q&A will give you an overview of IBS and how it differs from IBD.



Irritable bowel syndrome (IBS) is classified as a *functional* gastrointestinal disorder, which means there is some type of disturbance in bowel function. It is not a disease, but rather a *syndrome*, defined as a group of symptoms. These typically include chronic abdominal pain or discomfort and diarrhea, constipation, or alternating bouts of the two. People with IBS are also more likely to have other functional disorders such as fibromyalgia, chronic fatigue syndrome, chronic pelvic pain, and temporomandibular joint (TMJ) disorder.

IBS has been referred to by many names, including mucous colitis and spastic colitis, but these terms are inaccurate and lead to confusion about what IBS is. While the word "colitis" refers to an inflammation of the colon (large intestine), IBS does not cause inflammation. Unlike ulcerative colitis patients, IBS sufferers show no sign of disease or abnormalities when the colon is examined.

IBS does not produce the destructive inflammation found in IBD, so in many respects it is a less serious condition. It doesn't result in permanent harm to the intestines, intestinal bleeding, or the harmful complications often occurring with IBD. People with IBS are not at higher risk for colon cancer, nor are they more likely to develop IBD or other gastrointestinal diseases. IBS seldom requires hospitalization, and treatment does not usually involve surgery or powerful medications, such as steroids or immunosuppressives.

IBS can, however, cause a great deal of discomfort and distress, and can severely affect an individual's quality of life. Its symptoms can range from mildly annoying to disabling -- impinging on a person's self-image, social life, and ability to work or travel. People with IBS are more likely to seek health care for both gastrointestinal and non-gastrointestinal complaints compared to people without IBS. It is estimated that IBS results in direct and indirect medical costs of over \$20 billion annually.

### Who Gets IBS?

According to the International Foundation for Functional Gastrointestinal Disorders ([www.iffgd.org](http://www.iffgd.org)), IBS affects at least 10% to 20% of adults in the U.S. -- mostly women -- and is second only to the common cold as a cause of absenteeism from work. It is the disorder most commonly diagnosed by gastroenterologists and one of the top ten most frequently diagnosed conditions among U.S. physicians. IBS usually begins in late adolescence or early adult life -- most often at times of emotional stress.



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1: Chin J Dig Dis. 2005;6(3):122-32.

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Irritable bowel syndrome and inflammatory bowel disease: Interrelated diseases?

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In the past inflammatory bowel disease (IBD), celiac disease and irritable bowel syndrome (IBS) were regarded as completely separate disorders. Now, with the description of inflammation, albeit low-grade, in IBS, and of symptom overlap between IBS and celiac disease, this contention has come under question. Is there true overlap between these disorders? Despite the limitations of available data one cannot but be struck by some areas of apparent convergence: IBD and celiac disease in remission, lymphocytic colitis and microscopic inflammation in IBS, in general, and, especially, in the post-infectious IBS category. The convergence between latent celiac disease and sub-clinical IBD, on the one hand, and IBS, on the other, appears, based on available evidence, to be somewhat spurious and may largely relate to misdiagnosis, a phenomenon which may also explain the apparent evolution of IBS into IBD in some studies. Similarities between IBS and lymphocytic colitis are more striking and less readily dismissed; as for IBS, well documented instances of progression of lymphocytic colitis to full-blown IBD are infrequent, suggesting a true separation between this disorder and classical IBD. Do IBS and lymphocytic colitis represent different responses to similar triggers? Will some of the 'inflamed' IBS subgroup be reclassified as part of the spectrum of lymphocytic colitis in the future? Will inflammation emerge as a common underlying factor in the pathogenesis of IBS? The answer to these and many questions must await further study of this fascinating area.

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rice, whole-grain breads and cereals (unless you have celiac disease), fruits, and vegetables may help.

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### Is IBS linked to other health problems?

As its name indicates, IBS is a syndrome—a combination of signs and symptoms. IBS has not been shown to lead to a serious disease, including cancer. Through the years, IBS has been called by many names, among them colitis, mucous colitis, spastic colon, or spastic bowel. However, no link has been established between IBS and inflammatory bowel diseases such as Crohn's disease or ulcerative colitis.

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### Points to Remember

- IBS is a disorder that interferes with the normal functions of the colon. The symptoms are crampy abdominal pain, bloating, constipation, and diarrhea.
- IBS is a common disorder found more often in women than men.
- People with IBS have colons that are more sensitive and reactive to things that might not bother other people, such as stress, large meals, gas, medicines, certain foods, caffeine, or alcohol.
- IBS is diagnosed by its signs and symptoms and by the absence of other diseases.
- Most people can control their symptoms by taking medicines such as laxatives, antidiarrhea medicines, antispasmodics, or antidepressants; reducing stress; and changing their diet.
- IBS does not harm the intestines and does not lead to cancer. It is not related to Crohn's disease or ulcerative colitis.

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### Hope through Research

The NIDDK conducts and supports research into many kinds of digestive disorders including IBS. Researchers are studying gastrointestinal motility and sensitivity to find possible treatments for IBS. These studies include the structure and contraction of gastrointestinal muscles, as well as the mechanics of fluid movement through the intestines. Understanding the influence of the nerves, hormones, and inflammation in IBS may lead to new treatments to better control the symptoms.

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